

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER: 75213**

**ADMINISTRATIVE**

APPROVAL PACKAGE SUMMAR FOR 75-213

ANDA: 75-213

FIRM: Spear Pharmaceuticals

DRUG: Tretinoin

DOSAGE: Cream

STRENGTH: 0.1% w/w

CGMP STATEMENT/EIR UPDATE STATUS: EER is Acceptable 10-5-98

BIO STUDY/BIOEQUIVALENCE STATUS: Bioequivalency and clinical study is satisfactory 11-26-98

METHODS VALIDATION: The drug product is compendial

STABILITY: The firm has submitted 3 month accelerated stability data at 75%RH and 12 months room temperature data at 60%RH in both tube sizes.

LABELING REVIEW STATUS: Labeling is satisfactory on 8/28/98

STERILIZATION VALIDATION: N/A

BATCH SIZES: The firm has submitted the master formula and manufacturing procedure for the intended production batch of \_\_\_\_\_ using the same equipment and procedure as the executed batch and using the same drug substance manufacture. The firm has provided a copy of the exhibit batch lot #613910 for

COMMENTS: The Application is Approvable

Reviewer: Nashed E. Nashed, Ph.D.

DATE: 12/3/98

Supervisor: Paul Schwartz, Ph.D.

*PS 12/4/98*

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